REMARKS

Claims 1, 2 and 4-25 are pending in the present application and are rejected.

Applicants' Response to Claim Rejections under 35 U.S.C. §103

Claims 1-8, 10, 11 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Christian (U.S. Patent No. 4,708,931) in view of Schembri (U.S. Patent Publication No. 2004/0087033), the Applicant's admitted prior art (APA) and either Wilding (U.S. Patent Application Publication No. 2006/0223166), Anderson (U.S. Patent Application Publication No. 2005/0202504) or Childers (U.S. Patent Application Publication No. 2004/0086872).

It is the position of the Office Action that Christian discloses the invention as claimed, with the exception of the biopolymers and biopolymer solutions being transferred sequentially from a storage area to a preprocessing area to a detection area to a waste reservoir in a time-differentiated manner, and the teaching of the substrate being formed using an elastic material. The Office Action relies on Schembri to teach the elastic substrate, and relies on either the APA, Wilding, Anderson or Childers to teach the sequential transferring.

The Office Action alleges that it would have been obvious to modify the existing structure of Christian to include a new sample inlet port, collection area and preprocessing area, while maintaining the existing wash chambers of Christian. The proposed modification is illustrated on page 13 of the Office Action. While the Office Action explicitly states that wash chambers 123 and 125 should be retained, it is unclear what the Office Action regards the role of

detection solution chamber 124 would be in the proposed combination. In this proposed modification, a new sample inlet, collection area and preprocessing area are sequentially arranged upstream of the position where the conduits 131, 132 and 133 meet the microassay rod 10.

The proposed modification of Christian would render Christian unsatisfactory for its intended purpose

Applicants respectfully submit that the proposed combination of references suggested by the Office Action would give rise to significant problems. For example, in the claimed invention, a sealed waste chamber is included. However, if Christian was modified as per the suggestion of the Office Action, waste and/or sample solution would likely leak out of opening 126, thus creating a biohazard risk. Furthermore, if Christian were modified according to the suggestion of the Office Action, the sample solution would flow not only into a side of the microassay rod 10, but also would flow into the wash chambers 123 and 125, and the detection solution chamber 124. Finally, the solutions from wash chambers 123 and 125 and detection solution chamber 124 would flow into the proposed "pre-processing area."

Thus, the proposed modification of Christian would likely result in contamination of reagents and/or the sample. Further, the proposed modification would likely result in a reduction amount of sample detected in the microassay rod 10, because the sample would inevitably be diverted into the wash chambers 123 and 125 and the detection solution chamber 124. Since the intended purpose of the device of Christian is the accurate detection of samples, the proposed

modification would frustrate this intended purpose. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP 2143.01.

The proposed modification of Christian would change the principle of operation of the device of Christian ("parallel" vs. "series")

Additionally, Applicants respectfully submit that the proposed modification would require a complete redesign of the biochip. As noted above, MPEP § 2143.01 prohibits combination of references where the suggested combination of references would require a substantial reconstruction and redesign of the elements shown as well as a change in the basic principle under which construction was designed to operate. Applicants respectfully submit that the proposed modification would require changing the principle of operation from a biochip in which reagents are moved in "parallel" to one in which reagents are moved in "series." In fact, the proposed modification is actually a hybrid of a "parallel" device and a "series" device. In addition to requiring a substantial reconstruction and redesign of elements, this would give rise to problems, such as contamination, as discussed above.

The proposed modification of Christian would change the principle of operation of the device of Christian (pump vs. roller)

Each of Wilding, Anderson and Childers appear to disclose assay systems wherein a sample is sequentially moved from a collection area to a pre-processing area to a detection area. However, in each of Wilder, Anderson and Childers, the assays systems are complex, and involve PCR. Further, the movement between areas of the biochip in Wilder, Anderson and Childers is performed by an external pump or pressure difference, and not a roller. See Wilding, paragraph [0083]; Anderson, paragraphs [0179]-[0180]; Childers, paragraph [0099].

On the other hand, the Christian discloses that "no sophisticated machinery is required." Column 4, lines 9-10. Thus, one having ordinary skill in the art would not have been motivated to modify Christian to incorporate the teachings of Wilding, Anderson or Childers, since the teachings of these references require sophisticated machinery, such as an external pump. *Prima facie* obviousness is not established when the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." MPEP §2143.01, quoting *In re Ratti,* 270 F.2d 810, 813, 123 USPQ 349 (CCPA 1959).

<u>The proposed modification of Christian would change the principle of operation of the device of Christian (bag vs. tabular substrate)</u>

Similarly, the APA discloses moving a sample sequentially from a collection area to a pre-processing area to a detection area in Figures 5 and 6. However, the APA discloses in Figure 6 that the biopolymers are moved by a pair of rollers 61 and 62 on a blood collection bag 41. On

the other hand, the claimed invention requires that the biopolymers are moved by pressing a rigid roller on a flexible cover of a tabular substrate. Modification of Christian such that it was formed of a bag pressed by two rollers would require complete redesign of the device. As noted above, p*rima facie* obviousness is not established when the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." MPEP §2143.01, quoting *In re Ratti,* 270 F.2d 810, 813, 123 USPQ 349 (CCPA 1959).

Therefore, Applicants respectfully submit that it would not have been obvious to combine any of the APA, Wilding, Anderson or Childers with Christian and Schembri, since their methods of moving the samples are incompatible with each other.

It would not have been obvious to combine the teachings of Schembri with that of Christian

Similar to the discussion above with respect to Wilding, Anderson and Childers, the device of Schembri relies on an external pump to move the fluid. See paragraph [0087]. Furthermore, Applicants respectfully note that the Office Action states that "Schembri discloses an elastic substrate." However, Schembri only discloses a *flexible* substrate, and does not disclose an *elastic* substrate. "Flexible" merely means capable of being bent. See paragraph [0048] of Schembri. On the other hand, in the claimed invention, the elastic material may be squeezed, thus forcing a solution through a flow path.

Therefore, for at least the above reasons, Applicants respectfully submit that the claimed invention is patentable over the cited art. Favorable reconsideration is respectfully requested.

Claims 14-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Christian in view of Schembri, the Applicant's admitted prior art (APA) and either Wilding, Anderson or Childers, and in further view of Furcht (U.S. Patent No. 6,303,288).

It is the position of the Office Action that the combination of Christian, Schembri and either the APA, Wilding, Anderson or Childers teaches the invention as claimed, with the exception of teaching that the biochip cartridge is made separable into a first housing and a second housing that are detachably joined. The Office Action relies on Furcht to provide this teaching.

Furcht is directed at an integrated genetic testing system comprising a gene strip 11 and a test card 14. Gene strip 11 includes a sample collection pad 32, a reaction cocktail pouch 33, a sliding ferrule and collar 38. When gene strip 11 is inserted into access port 62 of test card 14, the reaction cocktail pouch is pierced, and the fluid contained therein is squeezed out by the collar 38. See column 9, lines 10-15. The sample is then amplified in the amplification chamber 63. Thus, the sample is moved from the sample collection pad 32 to the amplifier chamber 63 by squeezing. However, "[a]fter amplification, the amplified DNA sample is pumped by the pumps 17 through the transport capillary 64 to the detection sensing chamber 65 to commence a binding event." See column 11, lines 27-29. Additionally, it is noted that although the genestrip 11 is

used for collecting a sample, a process of extracting DNA and sterilization, as in the present invention, is not performed. Therefore, a sample obtained from the genestrip 11 is dangerous.

In response, Applicants respectfully submit that the combination of references does not disclose or suggest a separable biochip wherein the biopolymers are moved from a collection chamber to a preprocessing chamber to a detection chamber by a roller. The biochip of claim 14 is the same as that of claim 2, except that it is separable into two portions. However, Furcht, which the Office Action relies upon to teach a separable biochip, does not move the biopolymers using a rigid roller. While the sample is moved from the collection area to the pre-processing area in Furcht using a squeezing action similar to that of a roller, the moving of the sample to from the pre-processing area to the detection area is performed by pumps. Thus, Applicants respectfully submit that the system of Furcht is incompatible with the teachings of Christian, Schembri, the APA, Wilding, Anderson and Childers. Favorable reconsideration is respectfully requested.

Claims 19-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Christian in view of Schembri, the Applicant's admitted prior art (APA) and either Wilding, Anderson or Childers, and in further view of McGarry (U.S. Patent No. 6,642,046).

It is the position of the Office Action that the combination of Christian, Schembri and either the APA, Wilding, Anderson or Childers teaches the invention as claimed, with the

exception of teaching that a carrier is a glass slide. The Office Action relies on McGarry to provide this teaching.

McGarry is directed at a biochip having a substrate 22 which may be formed of a glass slide. A reaction chamber 30 is formed by an O-ring 48, a biochip (glass slide) 20 and a base plate 32. In response to the pending rejection, Applicants respectfully submit that it would not have been obvious to combine the teachings of McGarry with that of the other cited art. McGarry specifically discloses that reaction chambers are loaded using a pipet, then sealed. See column 12, lines 31-45.

On the other hand, as illustrated in Figures 20A-C of the present invention and discussed at page 18, line 26 to page 22, line 24, the invention of claim 19 includes the previously recited roller and a glass slide. Applicants respectfully submit that since McGarry discloses introduction of biopolymers using a pipet and subsequent sealing, it is incompatible with the teachings of claim 19, and all claims dependent thereon. Favorable reconsideration is respectfully requested.

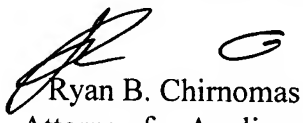
For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

Should the Examiner deem that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



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Enclosure: Petition for Extension of Time